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Tension-free Vaginal Tape for the Treatment of Urodynamic Stress Incontinence: Efficacy and Adverse Effects at 10-Year Follow-Up

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Abstract

Background: One of the most effective and popular current procedures for the surgical treatment of stress urinary incontinence (SUI) is tension-free midurethral slings.
Objective: To evaluate the outcomes of women with retropubic tension-free vaginal tape (TVT) for urodynamic stress incontinence (USI) after 10-yr follow-up.
Design, setting, and participants: This was a prospective observational study. Consecutive women with proven USI were treated with TVT. Patients with mixed incontinence and/or anatomic evidence of pelvic organ prolapse were excluded.
Intervention: Standard retropubic TVT.
Measurements: Patients underwent preoperative clinical and urodynamic evaluations. During follow-up examinations, women were assessed for subjective satisfaction and objective cure rates. Multivariable analyses were performed to investigate outcomes.
Results and limitations: A total of 63 women were included. After 10 yr, 5 patients (8%) were lost or no longer evaluable. The 10-yr subjective, objective, and urodynamic cure rates were 89.7%, 93.1%, and 91.4%, respectively. These rates were stable across the whole study period ($p > 0.99$). De novo overactive bladder was reported by 30.1% and 18.9% of patients at 3-mo and 10-yr follow-up, respectively (p for trend = 0.19). A total of 84.2% of women with detrusor overactivity received antimuscarinic drugs, but 43.8% were nonresponders 12 wk later. At multivariable analysis, maximum detrusor pressure during the filling phase >9 cm H_2O (hazard ratio [HR]: 16.2; $p = 0.01$) and maximum detrusor pressure during the voiding phase ≤29 cm H_2O (HR: 8.0; $p = 0.01$) were independent predictors for the recurrence of SUI, as well as obesity was for the recurrence of objective SUI (HR: 17.1; $p = 0.01$) and of USI (HR: 8.9; $p = 0.02$), respectively. Intraoperatively, bladder perforation occurred in two cases; no severe bleeding or other complications occurred.
Conclusions: The 10-yr results of this study seem to demonstrate that TVT is a highly effective option for the treatment of female SUI, recording a very high cure rate with low complications after a 10-yr follow-up.

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1. Introduction

Retropubic and transobturator tension-free midurethral slings (TVT and transobturator tape TVT-O) represent the most effective and popular procedures for the surgical treatment of stress urinary incontinence (SUI) and are currently considered the gold standard [1].

According to the last 2009 update of the International Consultation on Incontinence Guidelines, the surgical treatments of SUI may include the use of autologous slings, midurethral slings, and colposuspension. The guidelines do not define a clear priority among these three options [2,3]. Similarly, prospective studies, reviews, and meta-analyses [4–6] have highlighted the efficacy and safety of midurethral slings, showing their long-lasting benefits [7,8].

However, the lack of long-term outcomes of surgical procedures for the treatment of urinary incontinence is a major issue of debate in urogynecology. This condition deserves particular interest because life expectancy is significantly improving in the West; therefore data regarding the long-term durability of anti-incontinence procedures such as midurethral slings need to be addressed. To date the available evidence is still limited to only two other publications [7,9].

The aim of the present study is to report the long-term subjective, objective, and urodynamic outcomes of women with TVT with a follow-up of at least 10 yr to assess the efficacy for SUI and the safety of this procedure. We also investigated which factors were potentially involved in the risk of recurrence of SUI and the onset of de novo overactive bladder (OAB).

2. Methods

This prospective study was performed in a single urogynecologic unit at the University of Insubria, Varese, Italy. Between January 2000 and June 2001, we enrolled all consecutive women who complained about symptoms of pure SUI with proven urodynamic stress incontinence (USI). All the patients were candidates for surgery and scheduled for a retropubic TVT procedure (Gynecare; Ethicon, Somerville, NJ, USA). Exclusion criteria were as follows: women with previous history of anti-incontinence or radical pelvic surgery, psychiatric and neurologic disorders, concomitant vaginal prolapse higher than stage 1 according to the Pelvic Organ Prolapse-Quantitative (POP-Q) system [10], OAB symptoms, urodynamically proven detrusor overactivity (DO), and postvoid residual >100 ml.

Preoperative evaluation included medical history, physical examination, a frequency/volume chart, urinalysis, and complete urodynamic testing. The physical examination was performed with the patient in the lithotomic position, and pelvic organ prolapse (POP) was described during a maximal Valsalva maneuver according to the POP-Q system [10]. All women were evaluated with urodynamics (UDS) as previously described [11] (including uroflowmetry, filling cystometry, Valsalva leak point pressure [VLPP] measurement, and pressure/flow study) by a trained urogynecologist using a standardized protocol in accordance with the Good Urodynamic Practices Guidelines of the International Continence Society (ICS) [12]. Urethral hypermobility was defined in the case of a cotton swab test >30°. Patients were included regardless of the cotton swab and VLPP values. All methods, definitions, and units were updated in agreement with the last version ICS standardization of terminology [13].

All the TVT procedures were performed by the same surgeon according to the technique originally described by Ulmsten et al. [14]. The type of anesthesia used was general or spinal, in accordance with the anesthesiologic requirements and/or the patient's preference, as previously reported [15]. Follow-up evaluations were scheduled at 3 and 12 mo, and once per year thereafter, including anamnestic and physical examination, cough test, and evaluation of subjective satisfaction. A cough test was performed in the lithotomic and upright positions with a full bladder (ultrasonographic measurement of at least 400 ml). The objective cure was defined as the absence of urine leakage during a cough test. Subjective satisfaction was defined by using a 3-point symptom assessment scale (0, failure; 1, improved; 2, cured) filled out by the patient herself, as previously reported [16,17]. All women received UDS only at the 10-yr follow up visit, and UDS cure was defined as the absence of urine leakage during provocative maneuvers. Additional UDS, during the other follow-up examinations, was performed only in case of de novo OAB symptoms. For patients with OAB, tolterodine 2 mg twice daily was administered for at least 12 wk, and the efficacy was evaluated using the previously described 3-point symptoms assessment scale. Institutional review board approval and preoperative informed consent were obtained before the beginning of the study by our institution.

2.1. Statistical analysis

Statistical analysis was performed with SPSS v.17 for Windows (IBM Corp., Armonk, NY, USA). Continuous variables were reported as median and interquartile range; the chi-square and Fisher exact test were used to analyze proportions as appropriate. The student *t* test and the Mann-Whitney *U* test were performed to compare continuous parametric and nonparametric variables, as appropriate. The Cox proportional hazard model was used for univariable and multivariable analyses to evaluate factors potentially affecting the risk of recurrence (subjective, objective, and urodynamic).

Finally, multinomial logistic regression using the stepwise analysis was performed to investigate independent predictors of de novo OAB development. All the covariates that had p values ≤ 0.05 in univariable analysis were entered into the multivariate model using forward stepwise analysis. For both multivariable models, variables of interest were dichotomized either arbitrarily (ie, elderly: age ≥65 yr; obesity: body mass index [BMI] ≥30 kg/m^2) or using receiver operating characteristic curves (ie, UDS parameters). Statistical significance was considered achieved when $p < 0.05$.

3. Results

During the study period, 207 women were assessed for SUI at our department. Among these patients, 144 were excluded for the following reasons: 53 had mixed incontinence and 91 had concomitant evidence of POP. A total of 63 patients with proven USI who fulfilled the inclusion and exclusion criteria underwent the TVT procedure. Figure 1 displays the overall study flowchart. Table 1 summarizes the baseline characteristics of the study group.

Intraoperatively, bladder perforation occurred in two cases (3.8%). In both situations the bladder lesion was identified during the operation and the tape was promptly removed and replaced. No severe bleeding or other intraoperative complications occurred. No postoperative complications requiring surgical reintervention occurred.

At 10-yr follow-up, 58 cases (92.0%) were available for evaluation, whereas 5 patients (8.0%) were lost to follow-up or were no longer evaluable; 3 of them died for medical reasons not related to the TVT procedure (1 after the

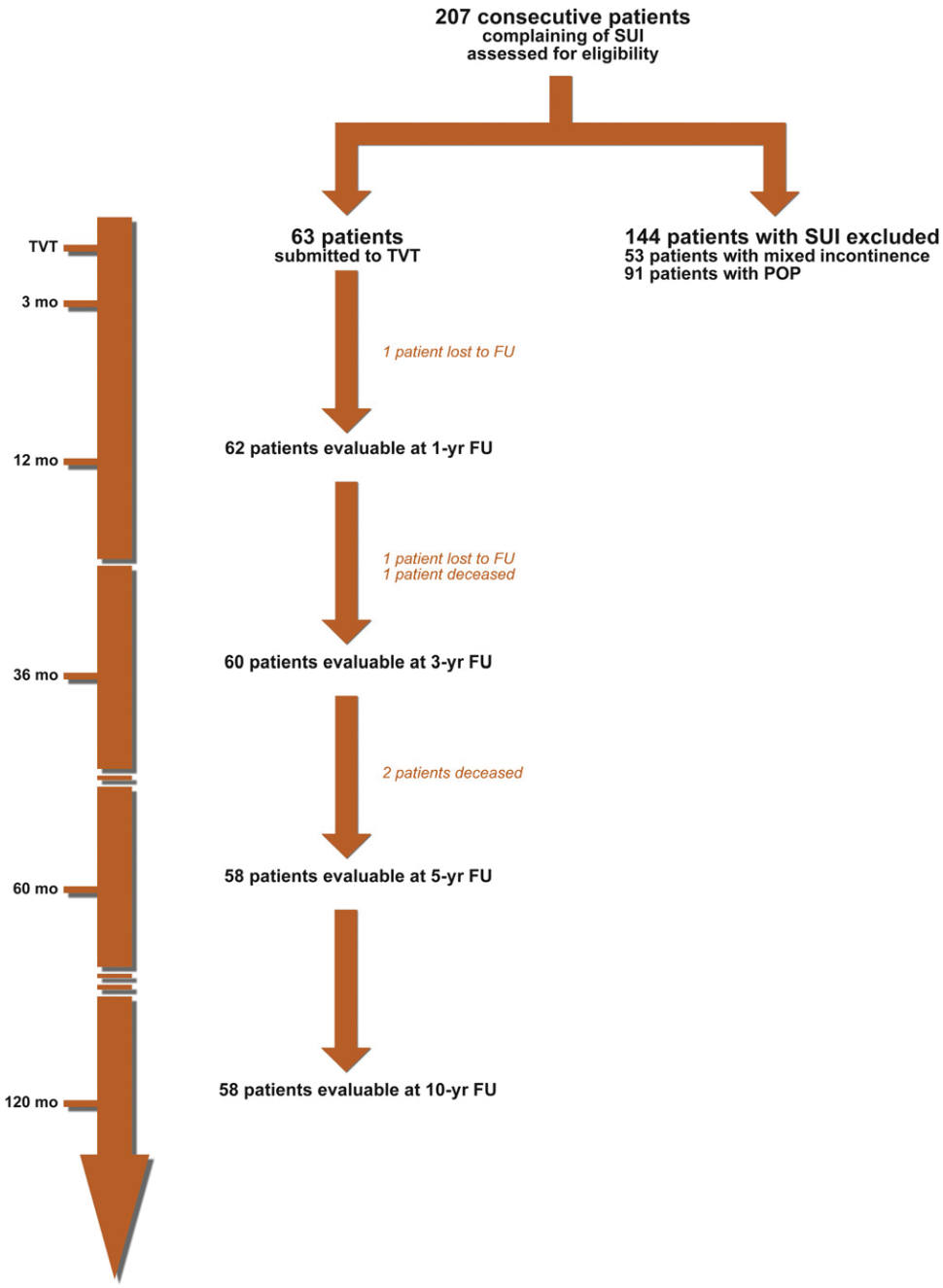

Fig. 1 – Progress of patients across the study period.
FU = follow-up; POP = pelvic organ prolapse; SUI = stress urinary incontinence.

first-year examination and 2 after the third-year examination, respectively), and 2 were lost to follow-up (1 after 3 mo and 1 after a year, respectively). However, at their last evaluation, these five women were subjectively and objectively cured.

Table 2 summarizes the subjective satisfaction and objective cure rate across the follow-up period. No significant deterioration of either subjective or objective outcomes was observed over time (all p values > 0.99). Ten years after surgery, 52 of 58 patients (89.7%) declared themselves satisfied, and 54 of 58 (93.1%) were at least improved. Similarly, at the last evaluation 54 of 58 women (93.1%) were objectively cured, and 53 of 58 (91.4%) also confirmed this finding at UDS.

Table 3 reports the univariable and multivariable analyses of factors potentially involved in the risk of recurrent subjective, objective, and UDS stress incontinence along the follow-up. Obesity, cystometric capacity, maximum detrusor pressure during filling and during voiding phases, maximum flow rate, intravesical opening pressure, and detrusor pressure at maximum flow rate were all significantly associated with subjective recurrent SUI in univariable analyses (all p values <0.05). On multivariable analyses, maximum detrusor pressure during the filling

Table 1 – Baseline characteristics[†]

	n = 63
Age, yr	58 (48–69)
BMI, kg/m^2	27 (26–28)
Obese: BMI ≥30 kg/m^2	9 (14.2)
Sexually active	42 (66.6)
Menopausal	45 (71.4)
HRT	18 (28.6)
Recurrent UTI	9 (14.2)
Previous vaginal deliveries	2 (2–3)
Macrosome (≥4000 g)	17 (27.0)
Operative delivery (vacuum/forceps)	7 (11.1)
Previous hysterectomy	7 (11.1)
Urethral hypermobility[*]	53 (84.1)
VLPP <60 cm H_2O	36 (57.1)

BMI = body mass index; HRT = hormonal replacement therapy; UTI = urinary tract infection; VLPP = Valsalva leak point pressure.
[†] Data are expressed as absolute number (%) or median (interquartile range).
[*] Cotton swab test >30°.

phase >9 cm H_2O (hazard ratio [HR]: 16.2; $p = 0.01$] and maximum detrusor pressure during the voiding phase ≤29 cm H_2O (HR 8.0; $p = 0.01$] at the preoperative UDS were the only independent predictors of recurrence of SUI. Obesity represented the only independent predictor of objective recurrence of SUI (HR 17.1; $p = 0.01$) and of recurrent USI (HR: 8.9; $p = 0.02$).

The onset of de novo OAB symptoms was reported by 30.1% (19 of 63) and 18.9% (11 of 58) at 3-mo and 10-yr follow-up, respectively. This proportion did not significantly change across the study period (p for trend: 0.19). All these women presented with dry OAB. At the UDS evaluation, 17 of 19 women (89.5%) had DO; 84.2% (16 of 19) of these women started an antimuscarinic treatment. Twelve weeks later, 43.8% (7 of 16) were nonresponders.

Univariable and multivariable analyses were performed to evaluate variables predicting the risk of de novo OAB at 3 mo and 10 yr. A first desire to void <190 ml (odds ratio [OR]: 7.1; $p = 0.01$) and a maximum detrusor pressure during voiding >28 cm H_2O (OR: 8.1; $p = 0.009$) at the preoperative UDS were both independent predictors for the onset of de novo OAB 3 mo after surgery. Similarly, a maximum detrusor pressure during the filling phase >8 cm H_2O (OR 7.9; $p = 0.02$) predicted the OAB at 10 yr (Table 4).

At 10-yr follow-up, comparing the pre- and post-TVT urodynamic data, we only found a significantly higher detrusor pressure during the filling and during the voiding phase; this finding reflects the onset of de novo DO in 17 women (Table 5).

During the final visit, voiding difficulties were reported in two patients. No patient required tape release or section during the 10-yr follow-up. No significant POP, vaginal, bladder, or urethral erosion, or de novo dyspareunia were noted in the remaining 58 patients.

4. Discussion

This study reports the combination of subjective, objective, and urodynamic outcomes of retropubic TVT at 10-yr follow-up. We found TVT to be a highly effective and safe procedure, with a long lasting effectiveness over time.

In the last decade, several publications have demonstrated the efficacy of this treatment at 1, 3, 5, and 7 yr [8,18–23]. However, for the comparison of the outcomes between the TVT and other historical procedures for the treatment of SUI such as open colposuspension, long-term follow-up is mandatory. In the present series the efficacy of TVT was also not affected in the long-term period. Such data are in agreement with the very few studies available in the

Table 2 – Analysis of cure rates across the study period

	3 mo	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	*p* value
Subjective outcomes												
Satisfied only	93.7 (59/63)	93.5 (58/62)	93.5 (58/62)	91.7 (55/60)	91.7 (55/60)	93.1 (54/58)	93.1 (54/58)	93.1 (54/58)	93.1 (54/58)	93.1 (54/58)	89.7 (52/58)	0.99[*]
Satisfied plus improved	95.2 (60/63)	95.2 (59/62)	95.2 (59/62)	93.3 (56/60)	93.3 (56/60)	94.8 (55/58)	94.8 (55/58)	94.8 (55/58)	94.8 (55/58)	94.8 (55/58)	93.1 (54/58)	0.99[*]
Satisfied only Assuming lost as failures	93.7 (59/63)	92.1 (58/63)	92.1 (58/63)	87.3 (55/63)	87.3 (55/63)	85.7 (54/63)	85.7 (54/63)	85.7 (54/63)	85.7 (54/63)	85.7 (54/63)	82.5 (52/63)	0.63[*]
Satisfied only Assuming lost as the last result carried forward	93.7 (59/63)	93.7 (59/63)	93.7 (59/63)	93.7 (59/63)	93.7 (59/63)	92.1 (58/63)	92.1 (58/63)	92.1 (58/63)	92.1 (58/63)	92.1 (58/63)	88.9 (56/63)	0.73[*]
Objective outcomes												
Objectively cured (at stress test)	95.2 (60/63)	95.2 (59/62)	95.2 (59/62)	91.7 (55/60)	91.7 (55/60)	93.1 (54/58)	93.1 (54/58)	93.1 (54/58)	93.1 (54/58)	93.1 (54/58)	93.1 (54/58)	0.99[*]
Objectively cured Assuming lost as failure	95.2 (60/63)	93.7 (59/63)	93.7 (59/63)	87.3 (55/63)	87.3 (55/63)	85.7 (54/63)	85.7 (54/63)	85.7 (54/63)	85.7 (54/63)	85.7 (54/63)	85.7 (54/63)	0.53[*]
Objectively cured Assuming lost as last result carried forward	95.2 (60/63)	95.2 (60/63)	95.2 (60/63)	93.7 (59/63)	93.7 (59/63)	92.1 (58/63)	92.1 (58/63)	92.1 (58/63)	92.1 (58/63)	92.1 (58/63)	92.1 (58/63)	0.99[*]
De novo OAB												
Onset of OAB	30.2 (19/63)	22.6 (14/62)	19.4 (12/62)	18.3 (11/60)	18.3 (11/60)	18.9 (11/58)	18.9 (11/58)	18.9 (11/58)	18.9 (11/58)	18.9 (11/58)	18.9 (11/58)	0.91[*]

OAB = overactive bladder.
[*] Chi-square test.

Table 3 – Uni- and multivariable analyses of variables potentially involved in the risk of recurrence of stress incontinence

Variable	Subjective recurrence of SUI				Objective recurrence of stress incontinence				Urodynamics recurrence of USI			
	Univariable analysis*		Multivariable analysis†		Univariable analysis*		Multivariable analysis†		Univariable analysis*		Multivariable analysis†	
	Hazard ratio (95% CI)	*p* value	Hazard ratio (95% CI)	*p* value	Hazard ratio (95% CI)	*p* value	Hazard ratio (95% CI)	*p* value	Hazard ratio (95% CI)	*p* value	Hazard ratio (95% CI)	Macrosome value
Elderly: age ≥65 yr	0.7 (0.1–3.4)	0.68	–		0.6 (0.1–5.5)	0.62	–		0.43 (0.04–3.8)	0.45	–	
Obese: BMI ≥30 kg/m^2	9.1 (1.1–71.5)	0.04	–	NS	17.1 (1.8–163)	0.007	17.1 (1.8–163)	0.01	8.9 (1.5–52.9)	0.02	8.9 (1.5–52.9)	0.02
No. of vaginal deliveries ($n \geq 2$)	0.8 (0.1–4.8)	0.83	–		0.99 (0.1–9.5)	0.99	–		0.5 (0.1–2.9)	0.44	–	
Macrosome (≥4000 g)	0.5 (0. 1–2.4)	0.35	–		0.5 (0. 1–2.7)	0.96	–		0.5 (0. 1–2.4)	0.35	–	
Operative delivery	0.2 (0.1–11.1)	0.90	–		0.2 (0.1–10.4)	0.97	–		1.8 (0.2–15.3)	0.62	–	
Menopausal	0.9 (0.1–4.8)	0.86	–		0.3 (0.04–2.4)	0.27	–		0.5 (0.1–2.9)	0.44	–	
HRT	0.9 (0.2–4.5)	0.88	–		0.9 (0.2–4.5)	0.88	–		0.9 (0.2–4.5)	0.88	–	
Recurrent UTI	1.01 (0.1–9.1)	0.98	–		1.01 (0.1–9.1)	0.98	–		1.5 (0.2–13.6)	0.69	–	
Previous hysterectomy	1.2 (0.1–12.0)	0.87	–		1.2 (0.1–12.0)	0.87	–		1.8 (0.2–15.9)	0.59	–	
Urethral hypermobility	0.4 (0.1–3.2)	0.39	–		0.6 (0.06–5.6)	0.64	–		0.3 (0.04–1.7)	0.17	–	
VLPP <60 cm H_2O	0.6 (0.1–2.7)	0.48	–		0.5 (0.05–4.6)	0.53	–		0.97 (0.2–5.8)	0.97	–	
FDTV (≤180 ml)	3.1 (0.6–11.6)	0.22	–		3.1 (0.3–29.8)	0.32	–		4.2 (0.5–16.9)	0.20	–	
CC (>480 ml)	1.9 (1.2–20.0)	0.03	–	NS	1.9 (0.2–13.2)	0.52	–		2.8 (0.5–16.9)	0.25	–	
$Pdet_{max}$ during filling phase (>9 cm H_2O)	8.4 (1.8–40.1)	0.007	16.2 (1.9–136)	0.01	4.7 (0.5–45.5)	0.17	–		6.4 (0.7–57.1)	0.09	–	
Q_{max} (≤24 ml/s)	6.0 (1.3–27.7)	0.02	–	NS	5.6 (0.3–28.7)	0.95	–		5.6 (0.3–28.7)	0.95	–	
I-OpenP (≤22 cm H_2O)	6.2 (1.3–28.3)	0.02	–	NS	6.2 (0.3–28.3)	0.95	–		2.6 (0.1–8.2)	0.95	–	
$Pdet_{max}$ during voiding (≤29 cm H_2O)	5.0 (1.04–24.2)	0.04	8.0 (1.5–41.0)	0.01	5.0 (0.1–14.2)	0.94	–		7.2 (0.8–64.4)	0.07	–	
$Pdet_{Qmax}$ (>28 cm H_2O)	2.1 (0.5–9.7)	0.30	–		0.95 (0.1–9.1)	0.96	–		1.8 (0.3–11.2)	0.48	–	

SUI = stress urinary incontinence; USI = urodynamic stress incontinence; CI = confidence interval; BMI = body mass index; HRT = hormone replacement therapy; UTI = urinary tract infection; VLPP = Valsalva leak point pressure; FDTV = first desire to void; CC = cystometric capacity; Q_{max} = maximum flow rate; I-OpenP = intravesical opening pressure; $Pdet_{max}$ = maximum detrusor pressure; $Pdet_{Qmax}$ = detrusor pressure at maximum flow rate.

* Univariate Cox proportional hazard model.

† Cox proportional hazard model with forward stepwise analysis.

Table 4 – Uni- and multivariable analyses of variables potentially involved in the risk of onset of de novo overactive bladder

Variables	De novo OAB after 3 mo				De novo OAB after 10 yr			
	Univariable analysis*		Multivariable analysis†		Univariable analysis*		Multivariable†	
	Odds ratio (95% CI)	p value	Odds ratio (95% CI)	p value	Odds ratio (95% CI)	p value	Odds ratio (95% CI)	p value
Elderly: age ≥65 yr	1.1 (0.3–3.4)	>0.99	–		0.4 (0.07–1.8)	0.30	–	
Obese: BMI ≥30 kg/m^2	1.1 (0.2–4.9)	>0.99	–		2.1 (0.4–10.1)	0.38	–	
No. of vaginal deliveries ($n \geq 2$)	1.2 (0.3–4.2)	0.76	–		0.5 (0.1–2.0)	0.43	–	
Macrosome (≥4000 g)	0.9 (0.3–3.0)	>0.99	–		1.6 (0.4–6.3)	0.71	–	
Operative delivery	0.9 (0.1–4.9)	>0.99	–		3.8 (0.7–20.6)	0.13	–	
Menopausal	0.6 (0.2–2.1)	0.52	–		0.9 (0.2–4.3)	>0.99	–	
HRT	0.8 (0.2–2.6)	0.77	–		0.8 (0.2–3.6)	>0.99	–	
Recurrent UTI	1.3 (0.3–6.2)	0.70	–		6.1 (1.2–30.4)	0.03	–	NS
Previous hysterectomy	1.7 (0.3–8.4)	0.67	–		4.0 (0.8–21.6)	0.11	–	
Urethral hypermobility	5.2 (0.6–44.7)	0.14	–		0.9 (0.2–5.1)	>0.99	–	
VLPP <60 cm H_2O	0.8 (0.3–2.4)	0.78	–		1.2 (0.3–4.6)	>0.99	–	
FDTV (≤190 ml)	4.2 (1.3–13.9)	0.025	7.1 (1.5–33.3)	0.01	1.3 (0.3–4.7)	>0.99	–	
CC (>496 ml)	0.2 (0.06–0.8)	0.046	0.2 (0.04–0.8)	0.02	0.1 (0.03–0.63)	0.01	0.1 (0.02–0.8)	0.01
$Pdet_{max}$ during filling phase (>8 cm H_2O)	3.3 (1.02–10.3)	0.053	–		6.6 (1.3–34.2)	0.02	7.9 (1.3–47.6)	0.02
Q_{max} (>17 ml/s)	1.5 (0.4–5.1)	0.56	–		2.6 (0.5–13.2)	0.31	–	
I-OpenP (≤28 cm H_2O)	21.3 (1.2–380.1)	0.002	–	NS	3.8 (0.4–32.9)	0.26	–	
$Pdet_{max}$ during voiding (>28 cm H_2O)	3.3 (1.2–11.2)	0.07	8.1 (1.7–39.5)	0.009	0.7 (0.2–2.9)	0.72	–	
$Pdet_{Qmax}$ (≤31 cm H_2O)	17.1 (1.02–306.4)	0.006	–	NS	3.1 (0.4–26.6)	0.43	–	

OAR = overactive bladder; CI = confidence interval; BMI = body mass index; HRT = hormone replacement therapy; UTI = urinary tract infection; VLPP = Valsalva leak point pressure; FDTV = first desire to void; CC = cystometric capacity; $Pdet_{max}$ = maximum detrusor pressure; Q_{max} = maximum flow rate; I-OpenP = intravesical opening pressure; $Pdet_{Qmax}$ = detrusor pressure at maximum flow rate.

* Fisher exact test.

† Binary logistic regression with forward stepwise analysis.

literature. Specifically, Nilsson et al. reported 11-yr follow-up data of TVT in 90 women with SUI that demonstrated objective and subjective cure rates as high as 90% and 77%, respectively [7]. Similarly, Olsson and colleagues found an objective cure rate of 84% and a subjective cure rate of 77% with 94% of the included patients satisfied with the results achieved [9]. However, a not negligible proportion of women included in these studies were evaluated during the last follow-up visit only by phone or by mail [7,9]. Conversely, to our knowledge, we present for the first time a comprehensive subjective, clinically objective, and urodynamic outcome of TVT at 10-yr follow-up. We also must emphasize that those women ($n = 6$) who were subjectively not satisfied after 10 yr in our study did not require any other surgical treatment.

Table 5 – Comparison of the urodynamic data†

	Preoperative UDS	UDS at 10 yr	p value*
FDTV, ml	180 (50–430)	195 (50–430)	>0.99
CC, ml	480 (220–500)	480 (220–500)	0.29
$Pdet_{max}$ during filling phase (cm H_2O)	8.4 (3–15)	9.5 (3–32)	0.001
Q_{max} (ml/s)	21 (7–77)	22 (7–67)	0.68
I-OpenP (cm H_2O)	23.4 (9–66)	23.2 (9–66)	0.98
$Pdet_{max}$ during voiding (cm H_2O)	31.5 (10–75)	32.1 (10–75)	0.01
$Pdet_{Qmax}$ (cm H_2O)	24.4 (8–60)	25.3 (8–59)	0.02

UDS = urodynamics; FDTV = first desire to void; CC = cystometric capacity; $Pdet_{max}$ = maximum detrusor pressure; Q_{max} = maximum flow rate; I-OpenP = intravesical opening pressure; $Pdet_{Qmax}$ = detrusor pressure at maximum flow rate.

† Data are expressed as median (range).

* Wilcoxon matched paired test.

The onset of de novo OAB symptoms, together with their progression and their possible treatment, is one of the most clinically relevant and largely debated postoperative complications of midurethral slings. Previous studies have reported de novo urgency rates ranging from 4% to 33% after TVT [5,20,24,25]. Discrepancies are related to the different definitions and questionnaires adopted to collect OAB symptoms, different demographic characteristics of the women included, and different concomitant surgical procedures associated with TVT. However, in our series we recorded a high prevalence of de novo OAB especially in the early postoperative period (about 30% at 3-mo follow-up). Conversely, we noted stable or even a lower prevalence of OAB symptoms over time, despite aging of the patients. For most of the patients complaining about de novo OAB, urodynamically proven DO was the underlining pathophysiologic condition. For the first time in the literature, we evaluated the efficacy of antimuscarinics in this particular type of symptomatic DO, identifying a cure rate lower than compared with idiopathic OAB [16,17,26]. At present the real efficacy of antimuscarinic treatment in OAB symptom subsequent to SUI surgery is difficult to define due to the lack of studies other than the present one. Such a crucial clinical issue deserves further investigation.

We have also considered several demographic, clinical, and urodynamic data to identify which factors could be involved in the risk of recurrence of stress incontinence or

development of de novo OAB. We found that women with a maximal detrusor pressure ($Pdet_{max}$) during voiding $\leq$29 cm H_2O at preoperative urodynamics were associated with a significantly higher incidence of SUI recurrence. We could speculate that in these women the lower $Pdet_{max}$ could reflect the lower pressure exerted to overcome urethral resistance during micturition, showing therefore a lower rhabdosphincter function. In our population, neither VLPP nor urethral mobility was an independent predictor for the recurrence of SUI. There are currently diverging opinions regarding the role of obesity on the outcomes of TVT [27–29]; in our population obesity was the only independent predictor of objective and urodynamic recurrence of stress incontinence, therefore confirming a significant association between BMI and the pathophysiology of SUI.

We also observed that higher preoperative detrusor pressure values (both during the filling and voiding phase) independently predicted the onset of de novo OAB. Comparing the urodynamic findings at the 10-yr follow-up with the preoperative data, we registered higher values of detrusor pressures, thus reflecting the onset of de novo DO.

The present study has several strengths including (1) a clinical and urodynamic evaluation performed in all patients 10 yr after TVT; (2) a highly homogeneous study population with the exclusion of women with mixed incontinence, DO, and/or any other associated surgical procedure; (3) the subjective and objective outcomes available for every year, and (4) the pre- and postoperative urodynamic evaluation. We acknowledge that a weakness of this study could be the limited sample size, even if patients were recruited in just one urogynecologic center, with an impressively low percentage of women lost to follow-up. For the present study no quantitative evaluation by any questionnaire was used because no validated instrument in Italian language was available in 2000. Another limitation of the present study is the three-item scale used to assess patients' perceptions of symptoms; it could be considered inadequate to detect small changes in patient conditions. However, Burgio et al. [30] reported a comparison among three subjective outcome tools as a secondary analysis of data from three randomized controlled trials testing interventions for incontinence. They evaluated a patient satisfaction questionnaire (a three-item scale) similar to the one we used in this study, a global perception of improvement (a five-item scale), and an estimated percentage of improvement (a scale from 0% to 100%). They concluded that all three of these instruments have "acceptable convergent and discriminant validity for measuring outcomes in studies of treatment for urinary incontinence" [30]. Finally, due to the limited number of events, we were forced to use stepwise multivariable models, which are well known to inflate the prognostic role of the covariates left in the models. However, a different choice would have resulted in overfitted models.

5. Conclusions

The long-term results of this prospective observational study seem to demonstrate that the TVT is a highly effective option for the treatment of female SUI. Indeed, we recorded very high cure rates and low complication rates over the 10-yr observation. The early postoperative onset of de novo OAB symptoms, especially if persisting over the years, could be the most relevant clinical issue related to TVT.

Author contributions: Maurizio Serati had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Serati.
Acquisition of data: Serati, Cattoni, Braga.
Analysis and interpretation of data: Serati, Siesto, Torella, Cromi.
Drafting of the manuscript: Serati, Cattoni.
Critical revision of the manuscript for important intellectual content: Serati, Ghezzi, Vitobello, Salvatore.
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